

Message Text

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ORIGIN HEW-06

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TO AMEMBASSY NEW DELHI IMMEDIATE

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E.O. 11652: N/A

TAGS: TPHY, OSCI, TBIO, IN

SUBJECT: DHEW/PHS/NIH/SFCP AGREEMENT 01-024-N, COLLABORATIVE NEUROLOGIC STUDIES (BACHHAWAT, MUKHERJEE, AUSTIN) - OFFICIAL TRAVEL OF DR. JAMES AUSTIN

PASS TO ACTING SCIATT TERESITA SCHAFFER

REFERENCE: STATE 94910

1. NIH WAS UNABLE TO TRANSMIT REFTEL AND EXPLANATORY LETTER TO DR. AUSTIN FOR DISCUSSION BEFORE HIS DEPARTURE. WHEN DR. AUSTIN CALLS AT EMBASSY TO ARRANGE FOR PER DIEM, SCIATT IS REQUESTED TO GIVE HIM A COPY OF REFTEL FOR INFORMATION AND BACKGROUND DURING HIS DISCUSSION WITH DR. GOPALAN. COMPLIANCE WITH DHEW REGULATIONS ON PROTECTION OF HUMAN SUBJECTS WILL BE A MATTER OF CONCERN TO GOPALAN AND INDIAN SCIENTISTS IN THE CASE OF ANY SUBSEQUENT CLINICAL STUDIES THE ICMR PROPOSES TO NIH. SINCE SCIATT
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HAS OPENED DISCUSSION OF THESE REGULATIONS WITH DR. GOPALAN IN THE CASE OF SUBJECT PROPOSAL, NIH RECOMMENDS THAT SCIATT PARTICIPATE WITH DR. AUSTIN IN DISCUSSION OF THIS SUBJECT WITH DR. GOPALAN. FOR EMBASSY GENERAL INFORMATION, NIH HAS ON OCCASION DISCUSSED THESE DHEW POLICIES WITH SOME INDIAN CLINICAL INVESTIGATORS VISITING NIH, AND THEY

HAVE WELCOMED THEM AS FULFILLING A NEED BY SETTING STANDARDS WHICH WOULD HAVE BEEN DIFFICULT TO ESTABLISH OTHERWISE. FROM SUCH COUNTRIES AS POLAND, YUGOSLAVIA, AND EGYPT, NIH RECEIVES ASSURANCES WHICH ARE IN GOOD FORM WITH A MINIMUM OF DIFFICULTY.

2. A TEXT OF A LETTER TRANSMITTING REFTEL TO DR. AUSTIN IS GIVEN BELOW. SINCE THIS CONTAINS ADDITIONAL BACKGROUND WHICH DR. AUSTIN SHOULD HAVE FOR DISCUSSIONS DURING HIS VISIT, EMBASSY IS ALSO REQUESTED TO MAKE A COPY OF THIS CABLE AVAILABLE TO HIM UPON ARRIVAL.

3. QUOTE: A CABLE HAS BEEN RECEIVED IN THIS OFFICE FROM THE AMERICAN EMBASSY IN NEW DELHI ASKING FOR A STATEMENT OF THE OBJECTIVES OF YOUR TRIP, AND THE NIH DECISION ON PROPOSAL TO BE CONVEYED TO DR. GOPALAN WHO HAD REQUESTED IT FROM THE EMBASSY. I HAVE SENT A CABLE TO THE EMBASSY, A COPY OF WHICH HAS BEEN FORWARDED TO YOU FOR YOUR INFORMATION AND GUIDANCE DURING YOUR TRIP.

4. IT IS ESSENTIAL THAT A DEFINITE DECISION BE MADE ABOUT THIS PROJECT AND THAT THE NIH, ICMR, YOU, AND THE EMBASSY ARE AWARE OF THE NIH POSITION. IN SEVERAL COMMUNICATIONS FROM THE EMBASSY, THE SCIENCE ATTACHE HAS INDICATED THAT DR. GOPALAN IS NOT AWARE OF THE SENSITIVITY AND IMPORTANCE OF THE ASSURANCE CONCERNING PROTECTION OF HUMAN SUBJECTS
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AND DOES NOT AGREE THAT COMPLIANCE WITH DHEW REGULATIONS SHOULD BE A REQUIREMENT FOR NIH ACCEPTANCE OF THIS PROJECT. FOR THIS REASON, THERE IS NO ALTERNATIVE BUT FOR THE NIH TO WITHDRAW FROM FURTHER CONSIDERATION OF THE PROPOSAL, AS I HAVE STATED IN THE CABLE.

5. DURING YOUR TRIP, I BELIEVE YOU SHOULD DEVOTE YOUR DISCUSSIONS TO THE TWO ALTERNATIVES OUTLINED IN THE CABLE - EITHER CONVINCE DR. GOPALAN TO SUBMIT A NEW AND COMPLETE APPLICATION WITH CONTROVERSIAL, OR POSSIBLY ILLEGAL, COMPONENTS REMOVED OR USE ICMR FUNDS TO SUPPORT DRS. BACHHAWAT'S AND MUKHERJEE'S PROJECT.

6. THE EMBASSY HAS REPORTED THAT DR. GOPALAN HAS BEEN PREOCCUPIED WITH GETTING ACCESS TO RESEARCH FUNDS FOR USE AT HIS DISCRETION. DR. GOPALAN HAS ASSUMED SUPPORT OF SOME PROJECTS FORMERLY SUPPORTED BY NIH AND OTHER DHEW AGENCIES AND, ALSO, FUNDED SOME NEW PROJECTS WHICH NIH HAD REVIEWED AND INTENDED TO SUPPORT. IT IS ON THE BASIS OF THIS KNOWLEDGE THAT WE HAVE OFFERED THE SECOND ALTERNATIVE GIVEN IN THE CABLE.

7. SINCE THE INITIAL "FREEZE" ON THE COLLABORATION IN

INDIA IN JULY 1972, ICMR AND OTHER INDIAN GOVERNMENT AGENCIES HAVE TURNED DOWN APPROXIMATELY 20 PROJECTS WHICH NIH HAD RECEIVED FROM INDIA AND APPROVED FOR FUNDING. SINCE THAT DATE, THE ICMR HAS APPROVED ONLY TWO PROJECTS WHICH NIH IS SUPPORTING. AT DR. GOPALAN'S REQUEST, NIH HAS SENT THREE TEAMS TO INDIA TO DEVELOP COLLABORATION AND WRITE RESEARCH PROPOSALS IN AREAS OF HIGH PRIORITY FOR INDIA, I.E., TUBERCULOSIS, LEPROSY AND STROKE, WHICH WERE AGREED TO DURING THE FIRST MEETING OF THE SUBCOMMISSION OF SCIENCE AND TECHNOLOGY IN JANUARY 1975. THE ICMR HAS SUBMITTED ONLY TWO PROPOSALS, ONE ON LEPROSY, WHICH WAS DEFICIENT IN ITS EXPERIMENTAL DESIGN, AND THE OTHER ON UNCLASSIFIED

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STROKE, WHICH RECEIVED A QUALIFIED APPROVAL FROM NIH. ALTHOUGH DR. GOPALAN'S SUPERIORS IN THE MINISTRY OF HEALTH GAVE DR. DONALD TOWER, DIRECTOR OF NINCDS, THEIR VERBAL ASSURANCE THE DECISION ON STROKE WAS ACCEPTABLE, DR. GOPALAN RESCINDED THIS AGREEMENT AND FUNDED THE PROJECT WITH ICMR FUNDS WITHOUT THE COURTESY OF INFORMING NIH. FOR THESE REASONS AND HIS VIEWS AND POLICIES MENTIONED IN MY LETTER TO YOU OF SEPTEMBER 29, 1977, I BELIEVE YOU WILL FIND HE IS FIRM IN HIS OPINIONS, AND THIS WILL LIMIT THE TYPE AND EXTENT OF THE COLLABORATION YOU CAN RE-ESTABLISH.

8. IN ADDITION TO THE KEY PARAGRAPHS IN THE REGULATIONS ON PROTECTION OF HUMAN SUBJECTS CITED IN THE CABLE, THERE ARE ALSO SOME RECOMMENDATIONS WHICH MAY RESULT IN REGULATIONS ALSO APPLICABLE TO DRS. BACHHAWAT'S AND MUKHERJEE'S PROPOSAL. THIS IS THE REPORT ON RECOMMENDATIONS ABOUT RESEARCH INVOLVING CHILDREN OF THE NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH ISSUED IN THE FEDERAL REGISTER JANUARY 13, 1978. I AM ENCLOSING A COPY FOR YOUR INFORMATION.

9. I AM SURE YOUR INDIAN ASSOCIATES WILL WELCOME YOUR VISIT AND I HOPE YOU CAN ESTABLISH A FEASIBLE BASIS FOR COLLABORATION AS THE RESULT OF YOUR TRIP. UNQUOTE CHRISTOPHER

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